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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,302	07/19/2001	Roberto A Macina	DEX-0180	6964

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/806,302

**Applicant(s)**

MACINA, ROBERTO A

**Examiner**

Anne Holleran

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 15, 18 and 21 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 16, 17, 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. The amendment filed 3/2/2005 is acknowledged.

Claims 1 and 11-21 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Maintained:***

3. Claims 1, 11, 12, 15, 18, and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer (Lehrer et al, U.S. Pub. NO.: US 2002/0034739) in view of either (Ni U.S. Patent 6,066,724; issued May 23, 2000; effective filing date Mar. 21, 1996; cited in the IDS) or Gentz (WO 97/34997; published 25 Sep. 1997; cited in the IDS) for the reasons of record.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant asserts that the basic criteria for the establishment of a prima facie case of obviousness have not been met, and supports this assertion by stating that Lehrer teaches away from methods where an increase in ESBPIII (referred to as lipophilin C in Lehrer) is used to indicate the presence of uterine or ovarian cancer in cells, tissues and bodily fluids. Furthermore, it is stated that Lehrer fails to teach a comparison step, where the levels of a polynucleotide encoding ESBPIII are compared in tissues, cells or bodily fluids from a sample to tissues, cells, or bodily fluids of a normal control. Applicant also points to the failure of Ni or Gentz to teach methods for detecting uterine or ovarian cancer.

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normal control. Applicant also points to the failure of Ni or Gentz to teach methods for detecting uterine or ovarian cancer.

Applicant appears to misunderstand the rejection. The rejection is based on the fact that the claimed methods include methods where measurements are made in bodily fluids. Therefore, the claimed methods read on detection of metastasis of uterine or ovarian cancer. Lehrer teaches methods for the detection of the metastasis of cancers and specifically points to cancers such as uterine or ovarian cancers (see paragraph 0011). Lehrer also teaches that bone marrow or blood cells fail to express the genes for lipophilins, and points out that the presence of lipophilins or the associated mRNA in the bloodstream is evidence for blood-borne dissemination of carcinoma cells originating from these organs (paragraph 0011). Therefore, Lehrer teaches a comparison step because the measured levels in the blood would have to be compared to a normal control. Ni or Gentz was cited because Lehrer's polynucleotide was not a 100% match with the polynucleotide of SEQ ID NO: 1. However, Lehrer's polynucleotide encoded the same polypeptide as is encoded by SEQ ID NO: 1, and the sequence of SEQ ID NO: 1 was known in the art prior to the filing date of the instant application as evidenced by the teachings of Ni or Gentz. Ni or Gentz generally contemplate diagnostic uses for a polynucleotide of SEQ ID NO: 1. Therefore, applicant's arguments fail to persuade because Lehrer in combination with Ni or Gentz appears to teach all of the method steps and because the relevant teaching of Lehrer is the detection of lipophilin C polynucleotides in the blood as a method to detect cancer metastasis.

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**Conclusion**

Claims 1, 11, 12, 15, 18, and 21 are rejected. Claims 13, 14, 16, 17, 19 and 20 are objected to depending from a rejected claim.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran  
Patent Examiner

May 12/2005



**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**

05/19/2005